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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/555,345 | 04/16/2008 | David Barshis | 63365US008 | 4521 |

32692 7590 03/29/2011

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| EXAMINER | |
|---|---|
| HAGHIGHATIAN, MINA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/29/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/555,345 | BARSHIS, DAVID | |
| | Examiner | Art Unit | |
| | MINA HAGHIGHATIAN | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *It is3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *11-13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13 and 15-17* is/are rejected.

7)☒ Claim(s) *15-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/01/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of the Amendments, remarks and an IDS filed on 02/01/2011. Claims 1-10 and 14 have been cancelled, claim 11 has been amended and new claims 15-17 have been added. Accordingly, claims **11-13 and 15-17** are pending and under examination.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### *Claim Objections*

Claims **15-17** are objected to for depending on a cancelled claim. Claim 1 has been cancelled. For examination purposes, claims 15 and 17 are interpreted as depending on claim 11. Corrections are required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim **17** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation of "the volume of the sponge is less than 8 $cm^3$" is **new matter** and has no support in the specification or original claims.

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim **16** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low" in claim 16 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification does not provide a definition for the term low viscosity and one of ordinary skill in the art would not be readily or reasonably apprised of the claimed scope.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 11-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grap et al (Duration of action of a single, early oral application of chlorhexidine on oral microbial flora in mechanically ventilated patients, XP-002506103) and evidenced by Peridex®, Drug facts, in view of Van Dyke et al (5,229,061).**

Grap et al teach that pneumonia is a common complication of mechanical ventilation and responsible for 90% of nosocomial infections in this population. Pneumonia is also the second most common nosocomial infection in the United States. Colonization of the oropharynx is one of the most critical risk factors for the development of nosocomial pneumonia in intubated patients (see introduction).

Grap et al disclose that after intubation, the endotrachial tube provides a pathway for direct entry of bacteria from the oropharynx through an open glottis to the lower respiratory tract (see page 84, col. 1, lines 18-23).

Grap et al disclose that use of a single application of CHG (2 ml of 0.12% as spray and **swab**) was tested in a study. The results suggest that use of CHG in the early post-intubation period may mitigate or delay the development of VAP. Specifically, a decline in the level of oral bacterial growth was found only in the treatment groups (see Discussion on page 88).

Grap et al teach application of chlorhexidine gluconate to the oral mucosa via a swab for control of nosocomial infections, however lack disclosure on the specific swab applicator of the instant claims. This deficiency is cured by Van Dyke et al.

According to Drug information Online, **Peridex®** mouthwash contains 0.12% chlorhexidine gluconate and 11.6% alcohol.

**Van Dyke et al** teach a dispensing applicator comprising hollow tube. The applicator includes a body portion containing a flowable substance within its cavity, which is sealed at one end, and has a frangible portion at its other end, to which the permeable member is attached. The frangible portion comprises a support element, through which extends a passageway connected at one end to the body portion cavity. A relatively rigid stem element extends outwardly of the support element, and a connecting element connects the base of the stem element and the outer end of the support element (col. 1, lines 53-60).

The body portion is cylindrical having a cross section substantially greater than the cross section of the frangible portion. The tube component may additionally include

a hollow portion interposed, and providing a passage, between the body portion and the frangible portion (col. 2, lines 7-12). The applicator also includes a cotton bud **or** sponge, applied over the frangible end of the tube (col. 3, lines 65-68).

The choice of material will depend largely upon the application for which the applicator is intended and, more particularly, upon the composition and viscosity of the liquid or other flowable substance contained within the internal reservoir (col. 6, lines 17-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the teachings of Grap et al on applying chlorhexidine to oral mucosa via a swab for controlling infections of nosocomial type, to have looked in the art for other more specific types of swabs for a better and more effective application of the said chlorhexidine formulation to oral cavity with a reasonable expectation of successfully applying a solution of chlorhexidine and reducing nosocomial infections in patients at risk.

It has been held that "[w]hen an application simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent application claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the

analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742. Consistent with this reasoning, it would have been obvious to have selected a more efficient swab for application of chlorhexidine solution to the patents oral cavity as taught by the prior art disclosure, to arrive at a product/method "yielding no more than one would expect from such an arrangement".

**Claims 11-13, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al (6,290,984) in view of Raad et al (US 20030078242) and in further view of Van Dyke et al (5,229,061).**

**Tapolsky et al** teach a non water-soluble pharmaceutical carrier gel which adheres to mucosal surfaces, providing protection to the treatment site and delivery of pharmaceuticals to the site of application, surrounding body tissues and bodily fluids (see abstarct and summary).

The pharmaceutical component may be a bactericide or disinfectant such as **chlorhexidine** (see col. 6, lines 18-20). The solutions and gels may be prepared by various methods known in the art. The gel may be applied to the treatment site by spraying, dipping, or direct application by finger or **swab** (See col. 7, lines 32-55).

Tapolsky et al lacks specific disclosure on reducing nosocomial infections. However this deficiency is cured by Raad et al.

**Raad et al** teach that most **nosocomial infections** are caused by the contamination of medical devices. The endotracheal tube is considered a common vehicle for colonization/contamination leading to nosocomial pneumonia (see [0005] and [0006]). Raad et al teach a method of coating a medical device with an antiseptic composition (see [0023]). One suitable antiseptic agent include **chlorhexidine** (see [0016]). The antiseptic composition can coat or impregnate a surface (see [0021]). Suitable surfaces may be skin or **mucosal surfaces** (see [0028]).

Tapolsky et al and Raad et al, discussed above lack specific disclosure on a swab that has a hollow handle and a frangible tip. However this deficiency is cured by Van Dyke et al.

**Van Dyke et al**, discussed above, teach a dispensing applicator comprising hollow tube. The applicator includes a body portion containing a flowable substance within its cavity and a tip made of cotton bud or sponge (see above).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tapolsky et al on applying biocide compositions to mucosal surfaces with the teachings of Raad et al on applying

antiseptic (biocide) compositions to mucosal surfaces and medical devices for reducing nosocomial infections with a reasonable expectation of successfully preparing a biocidal composition applied on the mucosal surfaces of a patient by a spray or swab to manage infections, bacterial growth and to reduce nosocomial infections. Both references teach chlorhexidine as a suitable biocide. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

It also would have been obvious to one of ordinary skill in the art at the time the invention was made to have implemented the specifics of Van Dyke et alt's swab with the method of reducing nosocomial infections of the combined references because complete sterility is very important in reducing contamination during treatment and a self contained sealed chlohexidine swab would have been ideal for such treatment. In other words, the claims would have been obvious because the technique for improving a particular formulation was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

**Claims 11-13, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (Effectiveness of 0.12% chlorhexidine gluconate oral rinse in reducing prevalence of nosocomial pneumonia in patients undergoing heart surgery, AJCC) in view of Van Dyke et al (5,229,061).**

Houston et al perform a study with the objective that decreasing the levels of bacteria in the oropharynx should reduce the prevalence of nosocomial pneumonia and to test the effectiveness of 0.12% chlorhexidine gluconate oral rinse in reducing prevalence of nosocomial pneumonia in patients undergoing heart surgery. Houston et al conclude that although rates of nosocomial pneumonia were lower patients treated with Peridex™ (chlorhexidine gluconate) than in patients treated with Listerine, the difference was significant only in those patients intubated more than 24 hours who had the highest degree of bacterial colonization (see page 567 and 569).

Houston et al lack specific disclosure on application being made by a swab. However this deficiency is cured by Van Dyke et al.

**Van Dyke et al**, discussed above, teach a dispensing applicator comprising hollow tube. The applicator includes a body portion containing a flowable substance within its cavity and a tip made of cotton bud or sponge (see above).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Houston et al on a method of reducing nosocomial infections by applying a chlorhexidine gluconate formulation to their oral mucosa with the teachings of Van Dyke et al on a specific swab for applying compositions to surfaces with a reasonable expectation of successfully preparing and applying an antiseptic agent such as chlorhexidine gluconate applied on the mucosal surfaces of a patient by a swab to manage infections, bacterial growth and to reduce

nosocomial infections. One of ordinary skill in the art would have been motivated to have implemented the swab of Van Dyke et al for the application of chlorhexidine gluconate because many patients in hospitals are not able to do so by way of an oral rinse and as such a nurse would have to assist them. A swab would have been a logical application method. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

**Claims 1-13, 15-17 are rejected.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). Also, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 02/01/2011 prompted the new ground(s) of rejection presented in this Office action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616